K062467

NOV 2 2 2006

AxSYM® HoloTC
510(K) SUMMARY (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of CFR.

Preparation Date: 15th August 2006

Dr Erica Conway
Regulatory Affairs Manager
Axis-Shield Diagnostics, Ltd.
The Technology Park
Dundee DD2 1XA, Scotland, UK

Device Name:

Reagents:
Classification Name: HoloTC test system
Trade Name: AxSYM® HoloTC Immunoassay
Common Name: Holotranscobalamin test
Governing Regulation: 862.1810
Device Classification: Class II
Classification Panel: Chemistry
Product Code: CDD

Calibrators:
Classification Name: Calibrator, Secondary
Trade Name: AxSYM® HoloTC Standard Calibrators
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Controls:
Classification Name: Single (specified) analyte controls (assayed and unassayed)
Trade Name: AxSYM® HoloTC Control
Common Name: Control
Governing Regulation: 862.1660
Device Classification: Class I
Product Code: JJX

Legally marketed device to which equivalency is claimed:

Axis-Shield HoloTC Radioimmunoassay (K#030655)

Intended Use of Device:

AxSYM HoloTC assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of holotranscobalamin (HoloTC) in human serum and plasma on the AxSYM System. HoloTC is used as an aid in the diagnosis and treatment of vitamin B_{12} deficiency.

The AxSYM HoloTC Standard Calibrators are for the standard calibration of the AxSYM System when used for the quantitative determination of holotranscobalmin (HoloTC) in human serum and plasma.

The AxSYM HoloTC Controls are for the use in quality control to monitor the accuracy and precision of the HoloTC assay when used for the quantitative determination of holotranscobalamin (HoloTC) in human serum and plasma on the AxSYM System.

Description of Device:

AxSYM HoloTC is based on Microparticle Enzyme Immunoassay (MEIA) technology. The AxSYM HoloTC reagents and sample are pipetted in the following sequence:

SAMPLING CENTER

- Sample and all AxSYM HoloTC reagents required for one test are pipetted by the Sampling Probe into various wells of a Reaction Vessel (RV).
- A reaction mixture is formed by combining diluted sample and microparticles coated with Anti-HoloTC monoclonal antibody in the sample well of the RV.
- When human HoloTC antigen is present in the sample, it binds to the coated microparticles, forming antigen-antibody complexes on the microparticles.
- The Anti-TC Antibody:Alkaline Phosphatase Conjugate is pipetted into a second well of the RV.
- The HoloTC Wash Buffer is pipetted into a third well of the RV.
- The Matrix Cell Wash is pipetted into a fourth well of the RV.

The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center by the Processing Probe.

PROCESSING CENTER

- An aliquot of the reaction mixture, containing microparticles and bound antigen-antibody complex, is transferred to the Matrix Cell. The microparticles bind irreversibly to the glass fiber matrix.
- The Matrix Cell is washed to remove materials not bound to the microparticles.
- The Anti-TC Antibody:Alkaline Phosphatase Conjugate is dispensed onto the Matrix Cell and it binds with the antigen-antibody complexes.
- The Matrix Cell is washed to remove conjugate not bound to the microparticles.
- The substrate, 4-Methylumbelliferyl Phosphate, is added to the Matrix Cell. The alkaline phosphatase-labeled conjugate catalyzes the removal of a phosphate group from the substrate, yielding the fluorescent product, 4-Methylumbelliferone. This fluorescent product is measured by the MEIA optical assembly.

Comparison of Technological Characteristics:

The AxSYM HoloTC assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of HoloTC in human serum and plasma. The Axis-Shield HoloTC RIA is a competitive binding radioassay which uses a specific transcobalamin antibody to capture transcobalamin from the patient sample. The vitamin B_{12} bound to the captured transcobalamin is then measured by procedures commonly used in vitamin B_{12} assays.

Summary of Non-Clinical Performance:

The AxSYM HoloTC assay is substantially equivalent to the Axis-Shield HoloTC RIA radioassay in terms of precision, linearity, interferences and stability as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The AxSYM HoloTC assay demonstrated substantially equivalent performance to the Axis-Shield HoloTC RIA radioassay indicated by a method comparison with a correlation coefficient of 0.90.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Erica Conway
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Dundee DD2 1XA, Scotland, UK

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Re: k062467
Trade/Device Name: AxSYM® HoloTC REAGENTS, AxSYM® HoloTC STANDARD CALIBRATORS (A-F) and AxSYM® HoloTC CONTROLS (LOW and HIGH)
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B_{12} test system
Regulatory Class: Class II
Product Code: CDD, JIT, JJX
Dated: August 21, 2006
Received: August 24, 2006

Dear Dr. Conway:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

ADMIN 5.0 Product Classification - Indications for Use Statement

510(k) Number (if known):

Device Name: AxSYM® HoloTC REAGENTS, AxSYM® HoloTC STANDARD CALIBRATORS (A-F) and AxSYM® HoloTC CONTROLS (LOW and HIGH)

Indications for Use:

Reagents

AxSYM HoloTC assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of holotranscobalamin (vitamin B12 bound to transcobalamin) in human serum and plasma on the AxSYM System. HoloTC is used as an aid in the diagnosis and treatment of vitamin B12 deficiency.

Calibrators

The AxSYM HoloTC Standard Calibrators are for the standard calibration of the AxSYM System when used for the quantitative determination of holotranscobalmin (HoloTC) in human serum and plasma.

Controls

The AxSYM HoloTC Controls are for the use in quality control to monitor the accuracy and precision of the HoloTC assay when used for the quantitative determination of holotranscobalamin (HoloTC) in human serum and plasma on the AxSYM System.

For *in vitro* diagnostic use.

Prescription Use X (Part 21 CFR 801 Subpart D)	**OR**	Over-The-Counter Use _____ (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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